DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Los Angeles District

19701 Fairchild
Irvine, California 92612-2506
Telephone (949) 608-2900

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

August 30, 2005 W/L 18-05

Keith E. Vinnecour
President
Beverly Hills Prosthetics Orthotics, Inc.
6300 Wilshire Blvd., Suite 150
Los Angeles, CA 90048

Dear Mr. Vinnecour:

During an inspection of your firm located in Los Angeles, California, on March 1, 2005 through March 11, 2005, and a follow-up visit on May 19, 2005 to collect additional information, our investigator(s) determined that your firm manufactures several external assembly lower limb prostheses, limb orthoses and truncal orthoses. These products are devices within the meaning of section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. § 321(h)), because they are intended to affect the structure or any function of the body.

This inspection revealed that these devices are adulterated within the meaning of section 501(h) of the Act (21 U.S.C. § 351(h)), in that the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation are not in conformity with the Current Good Manufacturing Practice (CGMP) requirements of the Quality System (QS) regulation found at Title 21, Code of Federal Regulations (CFR), Part 820. Significant violations include, but are not limited to, the following:

1. Failure to establish, maintain and control a quality system that is appropriate for specific devices manufactured, as required by 21 CFR § 820.20. For example,

    - You do not have established procedures for conducting management reviews, and the dates of management reviews are not documented, as required by 21 CFR § 820.20(c).

- The management representative has not ensured that quality system requirements are effectively established and maintained, as required by 21 CFR §820.20(b)(3)(i). Specifically, you have not established procedures for complaint handling, management review, nonconforming product and document control.

2. Failure to establish procedures for conducting quality audits, and failure to conduct audits to verify that the quality system is effective in fulfilling the quality system objectives, as required by 21 CFR § 820.22. Specifically, you have not established a quality audit procedure and have not conducted quality audits to verify your quality system is effective.

3. Failure to establish and implement procedures for receiving, reviewing and evaluating complaints by a formally designated unit to ensure that all complaints are processed in a uniform and timely manner and failure to maintain complaint files, as required by 21 CFR § 820.198(a). Specifically, your complaint handling procedure does not include a procedure for analysis, response, and corrective action after receipt of a complaint. Furthermore, your "Beverly Hills Prosthetics Orthotics, Inc Handbook" states, under "Communication/Complaint Handling," that any complaint received shall be written on a grievance form and given to the President/CPO within 24 hours. However, the complaint procedure does not specify any follow-up to the complaint. In addition, complete complaint files are not maintained at a central location but were found in different locations.

4. Failure to establish and maintain procedures to control product that does not conform to specified requirements, as required by 21 CFR § 820.90(a). Specifically, you do not have an established procedure in place for handling nonconforming components and nonconforming finished products.

5. Failure to establish and implement procedures for document control, as required by 21 CFR § 820.40. Specifically, you have no document control procedure to ensure that only accurate and current versions of documents are used and that obsolete documents are not used.

In addition, your external assembly lower limb prostheses, limb orthoses and truncal orthoses are misbranded under Section 502(b) (21U.S.C. 352(b)) in that the devices in package form do not bear a label containing: (1) the name and place of business of the manufacturer, packer, or distributor and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count.

Finally, we received an annual registration on March 22, 2005, advising us that your facility is no longer a device establishment. However, the products identified above are devices and, consequently, your firm is required to register the facility, as well as list these devices,

even though they do not require the submission of a premarket notification. Because your firm no longer has a valid registration, you will need to complete and submit forms FDA 2891, Registration of Device Establishment and FDA 2892, Device Listing, available at http://www.fda.gov/cdrh/registpage.html.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations.

The specific violations noted in this letter and on the Form FDA-483 issued at the conclusion of the inspection may be symptomatic of serious underlying problems in your establishment's quality system. You are responsible for investigating and determining the causes of the violations found by the FDA. You also must promptly initiate permanent corrective and preventive action for your quality system.

Federal agencies are advised of the issuance of all warning letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no premarket approval applications (PMAs) for Class III devices to which the Quality System/GMP deficiencies are reasonably related will be approved until the violations have been corrected. Also, no requests for certificates to foreign governments will be granted until the violations related to the subject devices have been corrected.

You should take prompt action to correct the violations cited in this letter. Failure to promptly correct these deviations may result in regulatory action without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office within 15 working days of receipt of this letter of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be implemented.

If you have any questions regarding this letter, please contact Mariza M. Jafary, Compliance Officer at 949-608-2977.

Your written reply should be addressed to:

Pamela B. Schweikert
Director, Compliance Branch
U.S. Food and Drug Administration
19701 Faiorchild
Irvine, CA 92612-2446

Sincerely,

Alonza E. Cruse
District Director

Cc: State Department of Public Health
Environmental Health Services
Attn: Chief Food and Drug Branch
601 North 7th Street, MS-35
Sacramento, CA 94234-7320